ANDERSON EXHIBIT 8

TO

OPPOSITION TO EXCLUDE TESTIMONY OF EXPERT MARK G. DUGGAN PH.D.

Hughes Deposition Transcript Excerpt

Exhibit "1"

Hughes, Ph.D., James W. - Vol. II
Chicago, IL

May 6, 2009

		Page	2
UNITED STATES DIS	STRICT COURT		
DISTRICT OF MASS	SACHUSETTS		
IN RE: PHARMACEUTICAL)		
INDUSTRY AVERAGE WHOLESALE) MDL No. 1456		
PRICE LITIGATION)		
) Master File		
) No. 01-CV-12257-PBS		
THIS DOCUMENT RELATES TO:)		
) Subcategory		
) No. 06-CV-11337-PBS		
United States of America,)		
ex rel. Ven-A-Care of the)		
Florida Keys, Inc., v.)		
Abbott Laboratories, Inc.,)		
CIVIL ACTION NO. 06-11337-PF	BS) VOLUME II		
•			
Videotaped Deposit	tion of JAMES W.		
HUGHES, Ph.D., at 77 West Wa	acker Drive, 35th		
Floor, Chicago, Illinois, co	ommencing at the hour		
of 9:09 a.m. on Wednesday, N	May 6, 2009.		

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Page 342
                                                                                                     Page 344
                                                                  THE WITNESS: Because AWPs for each NDC
    sufficient, you would say well, they're not
                                                         1
 1
2
    sufficient because?
                                                         2
                                                             come from one of the compendia. That's the source
 3
          MR. BERLIN: Objection, form.
                                                         3
                                                             of shall we say the truth of what AWP is at any
 4
          THE WITNESS: He is saying that $10.16
                                                         4
                                                             particular time in any particular quarter in any
                                                             particular state. Although of course compendia
 5
    is an Abbott NDC and only an Abbott NDC. Right
                                                         5
                                                             are national, correct.
 6
    now his assurances are zero. All he is saying is
                                                         6
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                                                         7
                                                                  So if he says I have gone to the source
    that Abbott has an NDC that's $10.16.
 8
          What I'm arguing that he needs to do is
                                                         8
                                                             of truth for NDCs, excuse me, I've gone to the
                                                             source of truth for AWPs, I've gone to where the
 9
    to provide a basis for that conclusion. And one
                                                         9
10 way to do that would be to say I have gone to
                                                            Medicare carriers go to get AWPs, I've gone to the
                                                        10
11 where NDC AWPs reside, First Databank or the Red 11
                                                             compendia, and I have checked that compendia and
12 Book or whichever one is appropriate for the
                                                        12 at that time here's a list of the NDCs that have
13 system that he's using, I have examined this for
                                                        13 $10.16. Or the only one that has $10.16 is
14 the appropriate quarter and the appropriate time,
                                                        14 Abbott. Therefore, I am confident that when I see
and it is my opinion that only Abbott, or excuse
                                                        15 $10.16, that it is indeed an Abbott NDC, yes, an
me, here is all of the NDCs that have a price of
                                                        16
                                                             Abbott AWP I mean to say.
17 $10.16 at this time.
                                                        17
                                                                  The standard that you keep asking me
                                                            about is that he goes to the source of the data,
18 BY MR. LAVINE:
                                                        18
19
       Q. And on what objective basis are we going
                                                        19
                                                             the compendia, and verifies his heretofore
    to be able to say that --
                                                             assumption that $10.16 can only be an Abbott NDC.
20
21
          MR. BERLIN: Were you done with your
                                                            That's the standard.
                                                        21
22
    answer?
                                                        22 BY MR. LAVINE:
                                            Page 343
                                                                                                    Page 345
1
           THE WITNESS: No, not even close.
                                                         1
                                                                Q. And there's no general rule that you
 2
           MR. BERLIN: Can you please let the
                                                             could describe that would tell us when he's
                                                         2
 3
    witness finish his answer?
                                                         3
                                                             reached that point.
 4
          MR. LAVINE: Well, much of it's
                                                         4
                                                                A. Yes --
 5
    nonresponsive. And if we want to chance to finish
                                                         5
                                                                   MR. BERLIN: Objection, form.
 6
    this deposition today, we're losing it quickly.
                                                         6
                                                                   Go ahead.
 7
           MR. BERLIN: Okay. Well, go ahead and
                                                         7
                                                                   THE WITNESS: Yes. When you're doing
                                                             data analysis, you want your data to be as
 8
    let the record reflect the witness is not complete
                                                         8
9
    with his answer.
                                                         9
                                                             accurate as possible. That's the standard.
10
    BY MR. LAVINE:
                                                        10
                                                            BY MR. LAVINE:
       Q. What is the standard that you would
11
                                                                Q. So Professor Duggan has failed to state
                                                        11
12 apply to determine when Professor Duggan has
                                                             his assumptions, he's failed to support his
                                                        12
    demonstrated a sufficient basis for his
                                                             assumptions, and he's failed to demonstrate that
13
                                                        13
    assumptions?
                                                             his numbers were as accurate as possible?
14
                                                        14
15
       A. When he offers evidence that he has
                                                        15
                                                                A. He's failed to state his assumption,
                                                            he's failed to state his basis for his assumption,
16 checked the accuracy of his assumption, that
                                                        16
17
    $10.16 is only an Abbott NDC.
                                                             and he's failed to take feasible steps, reasonable
                                                        17
18
       O. And what is the standard to let us
                                                        18
                                                             steps, to verify the accuracy of his assumption.
19 decide when he has offered sufficient evidence to
                                                                Q. Is there any other standard that he's
                                                        19
                                                             failed to meet in that regard?
20 the effect that he's checked the accuracy of his
                                                        20
21 numbers?
                                                                   MR. BERLIN: Objection, form.
                                                        21
22
           MR. BERLIN: Objection, form.
                                                        22 BY MR. LAVINE:
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13 (Pages 342 to 345)

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Page 398 Page 400 and not a fraudulent price. take into account. 1 The states and the providers arrive at 2 For example, my criticism about his 2 treatment of MAC prices where MAC prices are MACs as their best estimate of the minimum amount 3 4 negotiated between providers and state Medicaid that providers can accept and still be willing to agencies in my opinion represent the state's best, participate in the Medicaid program. 5 the state's and the provider's best estimate, best 6 So it addresses the, these negotiated 7 7 MAC prices address these issues of cost attempt at finding a mutually agreeable price. 8 containment and access to the best of the states' So reimbursing at such a MAC price he 8 9 considers as being fraudulent. And I object to 9 abilities. that and say that a price that was arrived at 10 Q. Would it be fair to say that that's 11 through a considered state agency policy should 11 another example of a violation of the standard of needing to base your methodology on a realistic 12 not in a blanket sense simply be considered a 12 13 fraudulent price. 13 but-for world? 14 But he doesn't take any of the access A. Yes. I think that would be a fair way 14 15 issues, he doesn't take any of the viability 15 to characterize it, yes. Q. Does that also -- I'm sorry. Let me 16 issues, he doesn't take any of the state policy 16 17 issues that are raised throughout the deposition 17 start over. 18 testimony that he did not read, takes none of that 18 Are there any other standards that you 19 into account and simply performs this mechanical would say Professor Duggan has failed to meet in 19 20 here's the reimbursement that was paid, here's the connection with his, the criticism you say that 20 21 but-for reimbursement based on my but-for AWP, 21 his calculations were mechanical? here's the difference, absolutely everything else A. Yes. I think sitting here today, to the Page 401 Page 399 stays the same. best of my recollection, we've covered them all. 2 Q. But based on the methodology established 2 Q. Now, with respect to the selection of by Professor Duggan, you're not of the opinion the arrays that were used for the basis of an 3 3 4 that he applied his methodology incorrectly; extrapolation regarding, we talked about some of 4 5 right? 5 the other ones earlier that haven't shown the 6 A. He applied an incorrect methodology correct NDCs were in the arrays, haven't shown 7 correctly as he believes would I guess be the way 7 that Abbott's price is the only one who would have 8 to characterize my opinion. changed, et cetera. But you also talked about how 9 there were too few arrays and they were not Q. Right. 10 But under the methodology as he set it randomly selected. 10 11 up, if the price based upon a hundred twenty-five 11 So what is the economic principle that percent of the average was lower than the MAC, it you say Professor Duggan failed to meet in his 12 12 was appropriate to calculate it on the basis of selection or reliance upon those arrays? 13 13 14 that lower hundred twenty-five percent of the 14 A. In his reliance upon those arrays, as I 15 average price rather than the MAC? 15 believe I say in my report, he's using what 16 A. Well, yes. I mean he did what he said economists refer to as a sample of convenience, 16 17 he did. 17 using the data that are there as being 18 representative of the population without any But I'm objecting to the treatment of a 18

27 (Pages 398 to 401)

investigation or any assurance that such sample is

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indeed representative of the, in this case,

Q. So the rule that he's violated is that

population of arrays.

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19 MAC price as being fraudulent as opposed to being 19

a price negotiated between providers and the

states that takes into account all of these other

things that I'm objecting that Dr. Duggan doesn't

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if you're going to use a sample of convenience, 1 vou need to demonstrate that it's reasonable to do 2

3 so?

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A. Well, if you're claiming that your sample of convenience is representative, which is something that somebody might claim, you need to provide evidence that it is indeed representative.

If you are stuck with the sample that you're stuck with, then it also seems to me it's incumbent upon a researcher to examine the consequences for their analysis from the fact that their sample is not representative of the population.

14 Q. Are there any other principles or 15 methods that you say Professor Duggan should have applied in connection with his selection of the 16 arrays, the sample of arrays? 17

A. Well, I mean as I understand it, Dr. 18 Duggan did none of the selecting. As I understand 19 20 it, Dr. Duggan was provided with a set of arrays by the government. 21

22 So I think it mischaracterizes as I but there are formulas for figuring that out.

2 Q. But you haven't done that analysis in 3 this case?

A. No. I have not.

IL

5 O. Are there any other economic theories or techniques that Dr. Duggan failed to meet in 7 connection with his extrapolation for Medicare 8 damages based on the arrays?

A. Well, I mean this, and let's just keep something in mind, is that in his rebuttal report he talks about other studies that provide extrapolations and so on and so forth.

13 I have not had, I have not reviewed those studies, but I would imagine that those 14 15 studies provided some measure of statistical 16 accuracy for their extrapolations, as that would 17 be a standard practice.

The overarching criticism is that we 18 have no basis for concluding that Dr. Duggan's 19 estimates are too high, too low, or just right 20 because he's simply used the sample that was 21

22 provided to him, he's gone ahead and extrapolated

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understand what Dr. Duggan is saying because I don't believe he made any claim that he selected the arrays from -- let me put it differently.

If Dr. Duggan had twenty more arrays in his possession, I assume he would have used them. I'm not saying that he did have more. I'm saying that it's my understanding that he used only those that were given to him by the government.

9 So it's not a matter of Dr. Duggan 10 actually performing the selection but rather 11 uncritically using a sample of convenience without any checks as to the representativeness of the 12 13 arrays that he had been provided.

14 Q. What standard would you apply to determine that the arrays that were relied upon in 15 Dr. Duggan's analysis were too few in number? 16

17 A. There are, in statistics there are formulas for figuring out, I'm trying to remember, 18 19 it's been a long time, for figuring out minimum, something like minimum required sample size, something like that. 21 I'm sure I don't have the term right, 22

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according to his methodology, he comes up with a number and we have no way of knowing whether that 2

number is terribly accurate, wildly inaccurate, 3

4 whether that number if he was provided with

twenty-five different arrays and performed the 5 same analysis would he get a number that was 6

similar to the number that he got or not.

Nothing that he does do we have any measure as would be standard practice in any academic economics paper, do we have any measure 10 11 of accuracy of his estimates of his extrapolations or difference calculations. 12

13 Q. Okay. You received Dr. Duggan's actual report, supplemental report, and rebuttal report; 14 right? 15

A. Yes.

17 Q. But you weren't provided with any of the underlying materials related to those reports; 18

were you? 19

A. I don't know, no.

Q. So your opinion isn't based upon any 21 review of any of the materials that were used to 22

28 (Pages 402 to 405)

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IL

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Page 422

and to adjust the administration fees accordingly. 2

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That's part of the law. That's what Congress after it got done looking at all of the problems with the previous Medicaid system, that's the conclusion that the Congress came to. And came to after weighing all of the issues of cost containment as well as access.

We've been sitting here arguing, you've been arguing with me that I haven't taken into account everything that has changed.

11 Well, then we're in great agreement on 12 Dr. Duggan's report because that's my objection to 13 Dr. Duggan's report. He doesn't take into account everything that would have changed. 14

- Q. Do you agree that some of the changes 15 that would have been implemented in a but-for 16 world that complies with your standard would have 18 increased the dollar value of the damages in this 19 case?
- A. No. I don't reach that conclusion. 20
- 21 Q. Every single change that would have been made in your version of the but-for world would 22

his tremendously unrealistic but-for world, Dr.

Duggan has come up with a set of difference 3 calculations that are unreliable and inaccurate.

They could be higher, they could be lower. That's not what I'm here about. What I'm here about is that the ones he's come up with we have every reason to believe are not accurate.

Q. But when I asked you a few minutes ago about can you say sitting here today with a 10 reasonable degree of certainty that it's more or less likely, more likely than not that Professor 11 12 Duggan's damage figure is wrong, you said that you could reach that conclusion. 13

So my follow-up question is since you didn't actually do those numbers, is that just based upon your calculation in your head?

A. No. I've just been through this.

If administration fees go up, as they did under the MMA, as they did under the DRA, as they did when the Congress of the United States

20 looks at these systems, weighs issues of access,

21

weighs issues of cost containment, and comes to a Page 425

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have resulted in a lower damage figure?

A. Well, if, for example, a reduction of ingredient cost by ninety percent in a state would have led to an "X" percent increase in dispensing fees in order to keep the Medicaid system viable, then yes, I think the difference would have been smaller, not larger.

Q. Are there any factors at all that would 8 9 have been part of your but-for world that would have caused the dollar value of damages to move 10 11 upward?

12 A. Sitting here today, I don't know that, I can't say a hundred percent that there's not, but 13 the main ones, the ones that I have identified in 15 my report, all point to having lower damages, not higher damages.

16 17 I know that in his rebuttal report Dr. Duggan makes claim of some things that would be, 18 some changes that would be in my but-for world that would make damages higher, but that's fine. 20 That's not the issue. 21 22 The issue for me is that in constructing

conclusion, they've come to a conclusion that when

you lower your ingredient costs down to a level

resembling average selling price, that this cannot

be done without an increase in dispensing or

4 5 administration fees. 6 So taking that one by itself into account, which is again one of my principal

criticisms of Dr. Duggan's report, I do conclude 8 9 that I think his damage calculations would in fact

be smaller if, for example, his but-for world for 10

the MMA was, suppose the MMA had been implemented

fifteen years sooner, suppose the DRA had been 12

13 implemented fifteen years sooner, then what would the difference have been. 14

15 For some transactions it would be the 16 reimbursement might be higher, for some

17 transactions the reimbursement might be lower. I 18 don't know.

19 But since the decrease in ingredient costs as we see in the actual world, MMA and DRA 20 are more than offset by increase in administration 21

22 and dispensing fees, it is my conclusion that Dr.

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Q. All right. But when he extrapolates to other carriers and assume that they would have 2

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used Abbott AWPs in generally the same frequency as the ones that he actually had information on.

4 5 that's where you have a criticism?

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6 A. What I have a criticism on is him 7 looking in the claims data and saving oh, here's a 8 reimbursement of \$10.16, Abbott has an AWP of 9 \$10.16; therefore, this must be an Abbott product and Abbott must be in this array.

10 Q. And did you look at the information that 11 he provided through counsel to you, including his 12 Red Book analyses and Red Book documentation, to determine whether or not the Red Book was 14 15 reflecting Abbott at that price and only Abbott at 16 that price at that time?

17 A. He did not mention in his report that he 18 had done any such checking. And I did not review Red Book data from him that concluded in any way 19 that this was an Abbott price and only an Abbott price, that it was not possible for it to be 21 another price. 22

product, that I don't know, did he just check the matching the, the products that are the same size 3 and dose as the NDC he was looking at or did he look at other things that may have crept into the 4 array that might have had those prices since we 5

6 know that the arrays were constructed at times 7 with error.

Q. In the Medicaid side where you criticize his use of the nine state, as you call it, nine state sample to extrapolate to the remaining 10 states, what proportion of the total Medicaid 11 claims dollars for these drugs were encompassed by 12 13 those nine states?

A. I believe he says something like seventy 14 percent for the ten states. 15

O. For the ten states.

17 A. Right.

O. Okay. So in a normal sampling scenario 18 19 where you basically have a situation where you 20 take the largest participants in terms of the 21 quantity of things you're trying to evaluate and 22 you get up to seventy percent, are you saying

Page 603

Q. Did you study the list of materials on 1 the source log that was provided with respect to 2 3 Dr. Duggan? 4

A. I looked at the supporting documents that I felt I needed to look at.

6 Q. Did you look at the forty-five Red Book 7 excerpts that he had on that log?

A. I did not.

9 Q. Why not?

A. I didn't. 10

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Q. Okay. Did you look at anything else on 11 that log to see if it provided a basis for the 12 13 information since he was referring to those items?

A. Dr. Duggan claims in his report that 14 15 this must be an Abbott AWP.

Again, I understand from his rebuttal 16 17 report that he claims that he checked to make sure that they were Abbott AWPs. 18

Again, it's still unclear to me exactly 19 what he did check because there are things that 20 21 appear in the arrays by error, there are things that appear wrong dosage, wrong size, wrong

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that's not a sufficient sample size to extrapolate the remaining thirty percent?

A. I'm saying it's not been demonstrated that it's a sufficient sample size.

I mean suppose you have as your population of interest a room full of individuals and you want to look at their salaries? So you take the seventy highest paid people and then say okay, I'm going to take the average of that and extrapolate to the other people. Well, that may or may not work.

If you take seventy men and then try to extrapolate to thirty women, that may not work very well for you, all right. Precisely because 15 there's no effort to say that the seventy percent that I'm using as the basis of my extrapolation in 16 fact mimics the thirty percent that I'm

17 extrapolating to. 18

Let's take it differently. I'm from the 19 State of Maine, we're in the state of Illinois. 20 Illinois is one of his exemplar states. Is the 21

Medicaid reimbursement system in Maine identical

78 (Pages 602 to 605)

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1 have to think that the sample of nine states that 2 you're using is in fact representative of the 3 other thirty-nine states that you're extrapolating 4 to.

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Then that would go back to the author, and the author may come back and say here, here, I've done this, this, that, and the other thing, and here's why I believe it to be representative.

9 Then it would be up to me as a journal referee to say oh, okay, I get it, I agree with 10 him, that's adequate, or no, I don't think that's 11 adequate for whatever the following reasons would 12 12 13 be.

So I viewed my job, and nobody ever disabused me from it, that my task here was restricted to the same sorts of things that I do in my regular professional life when critiquing the work of a colleague is to look at the methods 19 that he used, look at how he performed his analysis, looking at the assumptions underlying 21 his analysis, looking at the steps that he took, the steps that he didn't take, looking at the

Page 615

realism of what he's done, and then passing a judgment and writing that up and handing it in, which is in effect what I've done here.

Q. Back to the seventy percent sample. Now that Dr. Duggan has done more

testing and more explanation in his rebuttal report I guess is what we call it here, did that provide at least some more insight as to the appropriateness of the seventy percent sample?

10 A. Well, as I pointed out here over the past couple of days, the rebuttal report did 11 12 provide some more insight, but it also raised some 13 other questions because it wasn't always clear from exactly what he, it wasn't clear from what he 14 15 was saying in the rebuttal report exactly what he was doing. 16

17 It just wasn't, it wasn't clear to me 18 that take, for example, the checking of the AWPs, like he says oh, I checked to make sure it was 19

right. Again, what did you check, how extensively 20

21 did you check? That wasn't clear. 22

And there were other instances like

that.

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Q. Can you tell the court today within a reasonable degree of certainty in your profession that Dr. Duggan's quantitative estimation, taking away the dispensing fee issue for a moment, but just his quantitative estimation of the Medicaid damages is materially in error?

A. Well, as is replete in my report is yes, I do believe it is materially in error.

Q. When you say material, can you quantify 10 11 that?

A. I have not made any attempt to quantify 13 that.

But yet he has made assumptions that have no basis, he's made claims of representativeness that he does nothing to support, and so on and so forth, as I list in forty-seven pages in my report, leads me to believe that his estimates are inaccurate and unreliable.

In fact, in his rebuttal report where he is attempting to address some of these concerns

where he instead of doing an extrapolation, he goes to the data, the claims data for the other 2 thirty-eight states, he comes and says well, look, 3 if I did it using the claims data it's actually 4 substantially higher estimate of difference than I 5 6 got from the extrapolation, which in my mind 7 supports my contention that his original 8 methodology was in fact inaccurate and unreliable 9 because when he did it using the actual data he claims he got a substantially different number. 10

Q. Yet you've done absolutely no quantitative work yourself to try to determine if those numbers are materially wrong, trying to determine how to quantify that?

MR. BERLIN: Objection, form.

THE WITNESS: Again, I've done here what economists do when critiquing the work of colleagues, is that I look at his methods, I look at his procedures, I look at the assumptions, I look at the basis of his assumptions, I look at 21 the reasonableness of his assumptions, I look at what he is substantiating, what he's not

81 (Pages 614 to 617)

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